

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/992,845	MCDONALD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to amendment filed 4/25/2005.
2.  The allowed claim(s) is/are 1,6 and 17-19 (renumbered 1-5).
3.  The drawings filed on 11/14/2001 and 7/22/2004 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All    b)  Some\*    c)  None    of the:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892)	5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>5/19/2005</u> .
3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____.	7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment
4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance
	9. <input type="checkbox"/> Other _____.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Beth Kelly on 6/01/2005.

The application has been amended as follows:

In the claims:

Claims 7-13 have been cancelled.

Claim 1 (currently amended) A method for production of recombinant human  $\alpha_1$ -antitrypsin [polynucleotide] polypeptide using semi-continuous culture of transgenic rice cells comprising a heterologous expression cassette comprising a polynucleotide encoding the human  $\alpha_1$ -antitrypsin [polynucleotide] polypeptide, wherein said polynucleotide is operably linked to a RAMy3D promoter, the method comprising the steps of measuring the induction medium pH, and after the induction medium pH increases, exchanging [an] the induction medium with a growth medium [after the induction medium pH increases], and isolating the recombinant expression product from the induction medium, wherein the recombinant expression product is a heterologous protein and the induction medium pH increase correlates with a high level of heterologous protein expression.

In Claim 6, line 1, delete "5" and insert --1--.

In Claim 6, line 2, delete "gene" and insert --polynucleotide--.

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In Claim 6, line 2, before “optimized” insert --codon--.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
May 17, 2005

*Russell P. Kallis*  
RUSSELL P. KALLIS, PH.D.  
PATENT EXAMINER